4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2017-D-5225]

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance entitled "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: Guidance for Industry." This guidance document provides our thinking on how importers of food for humans and animals can comply with the regulation on foreign supplier verification programs (FSVPs) issued on November 27, 2015. The guidance announced in this notice finalizes the draft guidance of the same title dated January 24, 2018.

DATES: The announcement of guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's

Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-D-5225 for "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The

Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Compliance Policy Staff, Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, CFSANCompliancePolicy@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of November 27, 2015 (80 FR 74226), we issued a final rule adopting a regulation on FSVPs for importers of food for humans and animals (FSVP final rule) (see, 21 CFR part 1, subpart L). The FSVP final rule implements section 301 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), which enables the Agency to better protect public health by helping to ensure the safety and security of the food supply.

Section 301 of FSMA added section 805 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384a) to require persons who import food into the United States to perform risk-based foreign supplier verification activities. In addition to directing FDA to issue regulations on the content of FSVPs, section 805 of the FD&C Act directs FDA to issue guidance to assist importers in developing FSVPs.

In accordance with section 805 of the FD&C Act, we are announcing the availability of a final guidance entitled, "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: Guidance for Industry." This guidance provides our thinking on how to comply with the FSVP regulation, including, but not limited to, requirements to analyze the hazards in food, evaluate a potential foreign supplier's performance and the risk posed by a food, and determine and conduct appropriate foreign supplier verification activities. The guidance also addresses how importers can meet the modified FSVP requirements for importers of dietary supplements, very small importers, importers of food from certain small foreign suppliers, and importers of food from countries whose food safety systems we have officially recognized as comparable or determined to be equivalent to that of the United States.

In the *Federal Register* of January 24, 2018 (83 FR 3443) we made available a draft guidance for industry entitled "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" and gave interested parties an opportunity to submit comments by May 25, 2018, for us to consider before beginning work on the final version of the guidance. We

received several comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes additional clarification regarding to what foods the FSVP regulation applies, what information must be included in the FSVP, who may develop and perform FSVP activities, what hazard analysis must be conducted, what foreign supplier approval and verification activities must be conducted, what requirements apply for importing a food for which the hazards will be controlled after importation, how FSVP records must be maintained, what FSVP requirements apply for imported dietary supplement components, and what FSVP requirements apply to very small importers or when importing food for certain small foreign suppliers. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated January 24, 2018.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: Guidance for Industry." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 1, subpart L have been approved under OMB control number 0910-0752.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-

guidance-documents, or https://www.regulations.gov. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: January 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-00391 Filed: 1/10/2023 8:45 am; Publication Date: 1/11/2023]